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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,850	09/19/2001	Waltraud Ankenbauer	5304	4731
22829	7590	01/30/2004	EXAMINER	
ROCHE MOLECULAR SYSTEMS INC			KIM, YOUNG J	
PATENT LAW DEPARTMENT			ART UNIT	
1145 ATLANTIC AVENUE			PAPER NUMBER	
ALAMEDA, CA 94501			1637	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,850

Applicant(s)

ANKENBAUER ET AL.

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The present Office Action responds the Amendment received on November 26, 2003.

Preliminary Remark

The Office acknowledges the cancellation of claims 1-4 and 8-17, canceled in the Amendment received on November 26, 2003.

Claims 5-7 are pending and are under prosecution therefore.

Information Disclosure Statement

The IDS received on November 26, 2003 is acknowledged. A signed copy of its corresponding PTO-1449 is attached hereto.

Drawings

The Office acknowledges that Drawings filed on May 25, 2001 are acceptable.

Claim Rejections - 35 USC § 102

The rejection of claims 5-7 under 35 U.S.C. 102(b) as being anticipated by Zhu et al. (Nucleic Acids Research, 1991, vol. 19, no. 9, pages 2511), made in the Office Action mailed on August 27, 2003 is withdrawn in view of the arguments presented in the Amendment received on November 26, 2003.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/192,902 (filed July 11, 2002; published as US 2003/0119150 A1, published June 26, 2003), hereto referred to as the '902 application. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant application has at least one common inventor to that of '902 application.

Claim 5 of the instant application is drawn to a composition comprising a first thermostable enzyme exhibiting 3'-5' exonuclease activity (as amended) but essentially no DNA polymerase activity and a second enzyme exhibiting DNA polymerase activity, said composition enhancing the fidelity of an amplification process in comparison to the use of the single second enzyme.

Claim 3 of the copending '902 application, is drawn to a composition for performing a nucleic acid amplification reaction which comprises a thermostable DNA polymerase; a thermostable 3'-5' exonuclease, and at least one primer for nucleic acid amplification, wherein

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said thermostable 3'-5' exonuclease is either an exonuclease III homologue or a mutated DNA polymerase with *no or reduced polymerase activity*.

Since claim 3 of '902 application discloses all of the required elements of claim 5 of the instant application, such composition would necessarily enhance the fidelity of an amplification process. Further, it is a well established practice in the art of amplification to use a exonuclease in an amplification to reduce contamination during PCR (an enhancing aspect of the amplification process), rendering the composition of instant claim 5 obvious over claim 3 of the '902 application.

While the composition of '902 application includes a primer which is lacking in the composition of instant claim 5, instant claim 5 is drawn to a composition *comprising* the recited elements, allowing for, "*inclusion of unspecified ingredients even in major amount*," (*Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948)), allowing for "additional, unrecited elements or method steps" which would, "*still form a construct within the scope of the claim*." (*Genentech, Inc. V. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997)), rendering instant claim 5 obvious over claim 3 of the '902 application.

With regard to instant claims 6-7, drawn to the second enzyme lacking proof reading activity, wherein said enzyme is defined as *Taq* polymerase, the limitations are also considered to be obvious in view of claim 3 of the '902 application because the composition of claim 3 comprises a thermostable DNA polymerase, wherein *Taq* polymerase are well known in the art of amplification to be a common agent in amplification process. Such knowledge is even acquiesced by Applicants, wherein the specification of the '902 application discloses:

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“The thermostable polymerase as the first component may be *any kind of DNA dependent or RNA dependent DNA polymerase, preferably Taq Polymerase*” (page 4, [0049]).

The instant specification is also in agreement with the above fact:

“It is *common practice* to use a formulation of a thermostable DNA polymerase comprising a majority component of at least one thermostable DNA polymerase which lacks 3'-5' exonuclease activity...e.g. *Taq polymerase*...” (page 3, lines 1-4).

Therefore, instant claims 5-7 are obvious over claim 3 of the '902 application for the reasons set forth above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

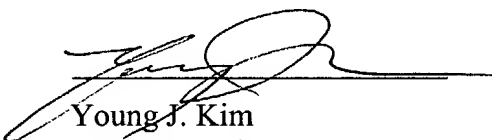
No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348 (effective January 14, 2004, changed to 571-272-0785). The Examiner can normally be

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reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905 (**effective January 14, 2004, changed to 571-272-0784**). If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (703) 746-3172 (**effective January 14, 2004, changed to 571-273-0785**). Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Young J. Kim
Patent Examiner
Art Unit 1637
1/24/04